



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

February 10, 2004

Areta L. Kupchyk, Esq.
Reed Smith, LLP
1301 K Street, N.W.
Suite 1100 – East Tower
Washington, DC 20005-3373

Dear Ms. Kupchyk:

Your petition on behalf of Jerome Stevens Pharmaceuticals, Inc. requesting the Food and Drug Administration to establish guidance and clarify requirements for abbreviated new drug applications with regard to levothyroxine sodium products was received by this office on 02/10/2004. It was assigned docket number 2004P-0061/CP 1 and it was filed on 02/10/04. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Lyle D. Jaffe
Division of Dockets Management
Office of Management Programs
Office of Management

